Comments in Opposition to WakeMed's Petition for an Adjusted Need Determination for a Linear Accelerator in Service Area 20 in the 2022 State Medical Facilities Plan

COMMENTER

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INTRODUCTION

WakeMed filed a petition for an adjusted need determination in the 2022 SMFP for one additional linear accelerator in Service Area 20, which includes Wake and Franklin counties. Rex Hospital, Inc. d/b/a UNC REX Hospital ("UNC REX") opposes the petition and requests that it be denied.

UNC REX'S RATIONALE FOR OPPOSITION

UNC REX believes that there are numerous reasons to deny the WakeMed petition. Most importantly, there is no evidence that the existing methodology fails to appropriately evaluate linear accelerator utilization and need in Service Area 20, which shows no need for an additional linear accelerator. To the contrary, and as described in more detail below, Service Area 20 has a significant surplus, which would be made even larger if the WakeMed petition is approved. Such approval would be contrary to the standard need methodology and contrary to the purpose of CON Law, which recognizes that the development of unnecessary health care services "results in costly duplication . . . with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services." NCGS § 131E-175(4). Another linear accelerator in Service Area 20 is simply unnecessary.

1. Surplus of linear accelerators

As WakeMed correctly notes, the methodology shows that Service Area 20 has a surplus of linear accelerators. What is not noted, however, is that <u>the surplus is the largest in the state</u>, with an excess of more than four linear accelerators, based on the procedures performed in the service area. Further, and contrary to WakeMed's statements, there are no "chronically underutilized" linear accelerators. One linear accelerator is currently located in Franklin County, and, while it was obtained prior the CON requirement for linear accelerators, Duke University Health System has received approval to acquire it and relocate it to Wake County. The second linear accelerator is approved for UNC Health and is the most recently approved additional linear accelerator in the service area. It was planned for development in Holly Springs; however, UNC Health subsequently obtained approval to locate it in the Panther Creek area of Cary. That project is under development, although it has been delayed due to the impact of the COVID-19 pandemic.

Further, WakeMed argues that there are "chronically underutilized" linear accelerators in the service area, and thus that the surplus noted in the *SMFP* data does not accurately reflect the needs of Service Area 20. First, contrary to WakeMed's statements, there are no "chronically underutilized" linear accelerators. Second, the linear accelerator methodology does not define "chronically underutilized," and if it did, it would likely not include either of these linear accelerators, given their current status. Finally, even if the methodology did exclude these machines, the surplus would still be greater than two linear accelerators, which clearly indicates there is more than sufficient capacity to meet the needs of the service area population for the foreseeable future.

Although WakeMed correctly notes that linear accelerator utilization increased from 2015 through 2020, data from 2018 to 2019, before the pandemic, shows that the growth is slowing. Moreover, even if the compound annual growth rate (CAGR) from 2015 to 2019 (5.8 percent) continues, Service Area 20's existing linear accelerators would still not exceed the 6,750 ESTV threshold until 2029, as shown below.

Year	Total ESTVs	Linacs	ESTVs/ Linac
2020	46,286	11	4,208
2021	48,965	11	4,451
2022	51,799	11	4,709
2023	54,798	11	4,982
2024	57,969	11	5,270
2025	61,325	11	5,575
2026	64,874	11	5,898
2027	68,629	11	6,239
2028	72,602	11	6,600
2029	76,804	11	6,982
CAGR	5.8%		

Thus, even if the growth trend from 2018 does not continue, with sustained long-term growth, Service Area 20 will not need another linear accelerator until at least the end of the decade, <u>after</u> <u>adding more than 30,000 ESTVs in utilization</u>—all of which can be accommodated on the existing linear accelerators in the service area.

2. WakeMed's Choices

WakeMed has been operating in Wake County for 60 years. At any time prior to 2006, WakeMed could have obtained a linear accelerator without a CON, as numerous providers across the state did, including one in Service Area 20. Since 2006, there have been need determinations for linear accelerators in 2007, 2009 and 2014 that added machines in Service Area 20. WakeMed could have taken these need determination opportunities and applied for a linear accelerator, but it did not. Since 2006, at least five linear accelerators in Service Area 20 changed owners, but WakeMed did not purchase any of them. Despite being a health system in the service area for many decades, WakeMed has chosen not to avail itself of numerous opportunities to obtain a CON for a linear accelerator to offer radiation oncology services. WakeMed is critical that two health systems

control all accelerators in the service area, but that outcome is due in large part to the choices WakeMed has made. While WakeMed presumably wants to begin providing the service, the SHCC should not ignore the significant surplus of linear accelerators in the service area. Approval of the WakeMed petition to add another linear accelerator would clearly result in unnecessary duplication of existing resources in the service area. Further, approval of WakeMed's petition would suggest that providers need not avail themselves of multiple opportunities to provide a service by applying for an allocation generated by methodology-driven need determinations, and instead merely petition for a special need determination despite previously electing not to apply under the standard methodology.

3. Service Area Changes

The petition focuses on growth in the service area, particularly in Wake County. UNC REX agrees that the area is growing, which impacts the need for more health services. However, that growth has not impacted linear accelerator utilization as it has other services, for multiple reasons. First and foremost, the population of Service Area 20 is roughly the same size today as it was in 2013eight years ago—despite the population growth. The reason for this is the extraction of Harnett County, which was part of Service Area 20 until 2014, when it reached the 120,000 populationthreshold needed to create its own service area. Since that time, Harnett County has been approved to obtain its own linear accelerator, and the remaining linear accelerators in Service Area 20 served a smaller population. According to Table 9I of the 2013 SMFP, Service Area 20, then including Wake, Franklin and Harnett, had a population of 1,129,916 and nine linear accelerators. Table 17C-5 in the Proposed 2022 SMFP shows that Service Area 20 has a current population of 1,189,588 and is served by 11 linear accelerators. Thus, in eight years, Service Area 20's population has increased only 60,000 people but has two additional linear accelerators. In comparison, Service Area 7 (the Charlotte area) has a population of 1.4 million, also served by 11 linear accelerators, and still has a surplus of one linear accelerator. Service Area 20 may need another linear accelerator in the future, but even with the projected population for 2026 shown in the petition, the population per linear accelerator would still be less than 120,000 and capacity would likely still be available on the existing linear accelerators.

4. Changes in Service Delivery

Another factor that impacts the need for linear accelerators is the way in which radiation therapy is delivered. While all providers may deliver care slightly differently, even for the same cancer site, some radiation therapy providers have moved towards providing the needed dose of radiation in fewer treatments (or fractions) or "hypofractionation." Due in part to improvements in linear accelerator technology that allows more accurate radiation delivery, treatments with higher doses per day can be given without significantly increasing side effects. As a result, patients that used to have 25 or 30 fractions are treated in as few as 10 or 15, or even fewer. This trend has anecdotally accelerated due to the pandemic, since patients were reluctant to spend more time than necessary in public or in healthcare settings. Providers also wanted to deliver the necessary treatment to patients without subjecting them to increased risk of COVID-19 exposure that might occur with a standard number of treatments (i.e., standard approaches result in a higher number of visits to the facility). So while population growth and cancer rates may increase the number of patients needing radiation, the utilization of the machines at providers with higher rates of hypofractionation is not increasing as much. Thus, the need for additional capacity is diminished,

despite the growth in patients, and this effect is shown in the standard methodology, which indicates a sufficient number of linear accelerators in the service area.

5. Geographic Distribution

The existing linear accelerators are also well distributed throughout Wake County. While the Franklin County linear accelerator was recently approved to be relocated, the other 10 linear accelerators are located or under development in multiple locations across the county, as shown in the map below.



Existing/Approved Radiation Therapy Locations in Service Area 20

As shown, the existing linear accelerators are dispersed throughout the county, with one of UNC Health's linear accelerators located only one block from WakeMed's main campus on New Bern Avenue. Thus, patients who present at WakeMed can receive radiation therapy at an existing facility right beside WakeMed, or at one of the many centers distributed throughout Service Area 20 (or elsewhere in the area; see section below on patient choice) that might be closer to their home.

6. Patient Choice

Despite the availability of linear accelerators across Wake County, many patients still choose to obtain radiation therapy in other counties. As shown by the patient origin reports from DHSR¹, 20 percent of Wake County patients sought radiation therapy outside the county in FY 2020, mainly in Durham and Orange counties, where academic medical centers exist. Whether stemming from patients working in other counties and choosing sites closer to their place of employment, or whether patients facing a cancer diagnosis would rather travel out of their home county to nearby academic centers, the result is less demand for Wake County residents within Wake County. Conversely, as shown in Table 17C-5, only 14.79 percent of patients treated on linear accelerators in the service area were from outside the service area. It is clear that another linear accelerator in Service Area 20 will not prevent patients from leaving the area for radiation if that is their preference, nor is it likely to provide increased access to patients from other service areas, given the already existing capacity of the linear accelerators in Service Area 20.

7. Continuity of Care

UNC REX agrees that patients need continuity of care, and sometimes that continuity is optimally provided by offering services within the same health system. WakeMed's petition does not demonstrate that any cancer patients in the area are not receiving high quality care in a coordinated manner. In fact, approval of the petition would likely result in less continuity of care for cancer patients. As the SHCC is likely aware, caring for cancer patients is ideally a multidisciplinary process, with a team of providers and caregivers working to ensure that the best treatment is provided, while the patient's psychosocial and spiritual needs are also addressed. For many patients, the first physician that discusses their diagnosis is a medical oncologist (hematologist/oncologist), who provides the treatment options and recommendations for care. medical As shown on WakeMed's website and its staff roster, WakeMed's hematologist/oncologists are primarily Duke physicians, along with two independent physicians in Cary, and it is UNC REX's understanding that all of WakeMed's cancer patients at its New Bern campus are treated by a Duke physician. Thus, the number of cancer patients that are actually diagnosed at WakeMed and begin their cancer journey without the involvement of a Duke physician is likely very small. Some UNC Health radiation oncologists also maintain various levels of privileges at WakeMed, both in Raleigh and Cary. While WakeMed refers to patients diagnosed with cancer in the Emergency Department as support for its petition, the percentage of patients diagnosed in that manner is minimal. The number of patients who need emergent radiation treatment for cancer is also low. And, for those cases, there is an existing radiation facility one block from WakeMed (see section above on geographic distribution).

Over the past few years WakeMed has chosen to align with Duke for oncology services. In 2017, WakeMed started a collaboration with Duke to provide cancer care, called Cancer Care+². WakeMed's own press release referred to this arrangement as:

¹ <u>https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2020/27-PatientOrigin_Linac-2020.pdf</u>

² <u>https://www.newsobserver.com/news/business/article145223679.html</u>

"a comprehensive, high-quality, fully integrated, value-based cancer care network – establishing a broad network of cancer care locations, enhancing access to oncology services and improving the coordination of cancer care for patients in Wake County.³"

WakeMed's audited financial statements for FY 2018 also referred to this arrangement and the positive benefit it was expected to have on the organization's financial results⁴. Although the petition does not address the status of this collaboration, WakeMed's public statements regarding its relationship with Duke clearly indicate that it believes high quality, integrated, value-based and coordinated care for cancer patients can be developed without WakeMed's ownership of an additional linear accelerator in the service area. And since these patients are already treated by a Duke physician at a WakeMed facility, if they also receive radiation at a Duke facility, then they would seem to already be part of a "fully integrated, value-based cancer care network" as WakeMed has described.

SUMMARY

UNC REX supports the standard methodology for linear accelerators and believes that it correctly shows no need for additional capacity in Service Area 20 at this time. WakeMed has chosen not to develop radiation oncology services despite numerous opportunities to do so. In contrast, UNC REX has diligently sought to develop its services and facilities in accordance with the CON regulations and process to ensure sufficient access to radiation therapy. UNC REX is currently constructing its new Cancer Center on Macon Pond Road, including replacement linear accelerators as well as thousands of square feet of space for clinics and support services. Contrary to WakeMed's implications in its petition, the mere development of an additional linear accelerator will not ensure high quality, coordinated care for cancer patients. Service Area 20 has access to multiple high quality cancer centers, both within the service area and beyond. UNC REX believes that the standard methodology is sound and appropriately reflects that there is not a need for another linear accelerator in the service area at this time. The SHCC should deny WakeMed's petition.

Thank you.

³ <u>https://www.wakemed.org/about-us/news-and-media/wakemed-news-releases/wakemed-and-duke-announce-cancer-care-collaboration</u>

⁴ https://emma.msrb.org/ER1184623-ER926564-.pdf